

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020898

MICROBIOLOGY REVIEW(S)

**REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805**

Microbiologist's Review #3 of NDA 20-898 Addendum
August 11, 1998

A. 1. **APPLICATION NUMBER:** 20-898

APPLICANT: Genzyme Corporation
1 Kendall Square
Cambridge, MA 02139-1562

2. **PRODUCT NAMES:** Thyrogen (throtropin alfa)

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Thyrogen consists of 2 vials: 1 vial of sterile lyophilized powder for injection containing 1.1 mg of thyrotropin for injection, and 1 vial of sterile WFI for reconstitution. Thyrogen is to be administered intramuscularly only.

4. **METHOD(S) OF STERILIZATION:**

5. **PHARMACOLOGICAL CATEGORY:** 1P; Thyrogen is indicated for use as an adjunct for the detection of thyroid remnants and well-differentiated thyroid cancer.

B. 1. **DATE OF INITIAL SUBMISSION:** December 12, 1997

2. **AMENDMENT:** February 23, 1998

3. **RELATED DOCUMENTS:**

4. **ASSIGNED FOR REVIEW:** March 9, 1998

5. **DATE OF CONSULT REQUEST:**

C. **REMARKS:**

The applicant sent two amendments dated 2/23/98 and 5/20/98.

D. CONCLUSIONS:

The final review for the NDA submission, Microbiology Review #2, included information from both Amendments dated 2/23/98 and 5/20/98. The conclusion does not changed the recommendation for approval made in Microbiology Review #2.

/S/

8/11/98

Brenda Uratani, Ph.D.
Review Microbiologist

/S/

8/11/98

APPEARS THIS WAY

cc:

NDA 20-898 Addendum
HFD-510/ Div. File
HFD-805/ Uratani
HFD-510/CSO/McCort
drafted by: Brenda Uratani, 8/11/98
R/D initialed by P. Cooney, 8/11/98

APPEARS THIS WAY
ON ORIGINAL

**REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805**

Microbiologist's Review #2 of NDA 20-898 Amendment
June 2, 1998

A. 1. **APPLICATION NUMBER:** 20-898

APPLICANT: Genzyme Corporation
1 Kendall Square
Cambridge, MA 02139-1562

2. **PRODUCT NAMES:** Thyrogen (throtropin alfa)

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Thyrogen consists of 2 vials: 1 vial of sterile lyophilized powder for injection containing 1.1 mg of thyrotropin for injection, and 1 vial of sterile WFI for reconstitution. Thyrogen is to be administered intramuscularly only.

4. **METHOD(S) OF STERILIZATION:** 

5. **PHARMACOLOGICAL CATEGORY:** 1P; Thyrogen is indicated for use as an adjunct for the detection of thyroid remnants and well-differentiated thyroid cancer.

B. 1. **DATE OF INITIAL SUBMISSION:** December 12, 1997

2. **AMENDMENT:** May 20, 1998

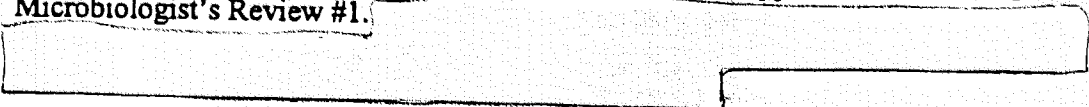
3. **RELATED DOCUMENTS:**

4. **ASSIGNED FOR REVIEW:** May 26, 1998

5. **DATE OF CONSULT REQUEST:** December 22, 1997

C. **REMARKS:**

The amendment responds to questions presented to the applicant as a result of Microbiologist's Review #1.



D. CONCLUSIONS:

All questions have been satisfactorily answered. The submission is recommended for approval with regard to microbiology.

APPEARS THIS WAY
ON ORIGINAL

/S/ 6/2/98

Brenda Uratani, Ph.D.
Review Microbiologist

/S/ 6/2/98

APPEARS THIS WAY
ON ORIGINAL

cc:

NDA 20-898
HFD-510/ Div. File
HFD-805/ Uratani
HFD-510/CSO/McCort
drafted by: Brenda Uratani, 6/2/98
R/D initialed by P. Cooney, 6/2/98